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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,323	07/14/2003	Lisa K. Jennings	20609/241 (PD 02036/02037	8249

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

Edwin V. Merkel
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,323	JENNINGS ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *1-71 and 76-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72, 74-75* is/are rejected.

7)☒ Claim(s) *73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 12/29/05 are pending.

2. Applicant's election with traverse of Group XLVII, claims 72-75 drawn to a polypeptide that is a fragment of human CD9 and a chimeric protein and SEQ ID NO: 3 as the species filed on 12/29/05, is acknowledged.

Upon reconsideration Examiner has extended the search to cover SEQ ID NOs: 4, 5 and 6.

Applicant's traversal is on the grounds that the product and process claims can be searched without undue burden. This is not found persuasive because the specific antibodies/peptides are recognized divergent subject matter. Further, the product and process claims are distinct as shown in the previous office Action mailed 9/29/05, and searches of all groups would place an undue burden upon the examiner due to the distinct and divergent subject matter of each Group. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-70, and 76-78 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 72-75 are under examination as they read on a polypeptide that is a fragment of human CD9 and a chimeric protein wherein the fragment is SEQ ID NOs: 3-6.

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration of the inventor Joseph T. Crossno, Jr. residence.

6. The specification is objected to for the following informalities: page 65, line 60 indicates that the amino acid sequence ^{168}P-I^{185} is peptide 6. However, said amino acid sequence is peptide 6**a**. Correction is required.

7. Applicant's IDS, filed 12/30/04, is acknowledged.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 72 and 75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide that is a fragment of human CD9 wherein the polypeptide is SEQ ID NO: 3-6, does not reasonably provide an isolated polypeptide that is a fragment of human CD9 and comprises at least 5 contiguous amino acids from amino acids 35-58 or human CD9 or amino acids 113-192 of human CD9 in claim 72, or a chimeric protein comprising the polypeptide according to claim 72 in claim 76. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

The specification does not provide a sufficient enabling description of the claimed invention. The specification discloses that the amino acid sequence SEQ ID NO:5 (peptide 6, ^{168}P-K^{192}) with a disclosed activity of inhibiting the binding of FN to CD9 (e.g., page 53 at lines 1-2). Further the specification on page 8, lines 30-31 discloses that the presence of both peptides 5b (claimed SEQ ID NO: 4, derive from EC2) and 6a (claimed SEQ ID NO: 6, derived from EC2) reversed the inhibitory influence of CD9 on A6 CHO cell adhesion to fibronectin. The specification (page 17, lines 15-16 and page 65, lines 19-24) further discloses that PKKDV (claimed SEQ ID NO: 3) is believed to be essential for mAb7/CD9 binding. The specification on page 56, lines 31-32 discloses that the data suggest that CD9 residues 168-192 (claimed SEQ ID NO:5) contain part, but not all, of the FN-binding sequences on CD9 EC2. Furthermore, the specification on page 61, lines 20-22 discloses that peptides 5b (claimed SEQ ID NO: 4) and 6a (claimed SEQ ID NO: 6) inhibited the immunopreciptiation of CD9 by mAb7. The common sequence PKKDV (SEQ ID NO: 3) of peptides 5b and 6a may be essential for mAb7/CD9 binding. The instant claims encompass in their breadth *any* fragment comprised comprising at least 5 contiguous amino acids from a amino acids 35-58 or human CD9 or amino acids 113-192 of human CD9 or a chimeric protein thereof.

However, there does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make and use the various amino acids recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential for inhibiting cell adhesion to fibronectin. Without detailed direction as to which amino acid sequences are essential to the function of the polypeptide fragment, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of amino acid sequences encompassed by the instant claims would share the ability to inhibit cell adhesion to FN of the polypeptide fragments of CD9, other than the nucleic acid of SEQ ID NO:5, and 4 and 6.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 72 is rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al (JBC, 270(41):24092-24099, 1995).

Shaw et al teach a polypeptide including amino acids 169-180 of the second external loop of CD9, said polypeptide is a fragment of human CD9 and comprised at least 5 contiguous amino acids from 113-192 of human CD9 (see page 24098, 1st col., lines 1-5 in particular).

The reference teachings anticipate the claimed invention.

12. Claims 72 and 74 is rejected under 35 U.S.C. 102(b) as being anticipated by US. Pat. No. 5,439,886.

The `886 patent teaches a polypeptide fragment comprises 30 amino acids from amino acids 114-143 of human CD9 (see patented SEQ ID NO: 4 and col., 21, under peptide 1 in particular). Further, the `886 patent teaches a polypeptide fragment comprises 29 amino acids form amino acids of 138-166 of human CD9 (see patented SEQ ID NO: 5 and col., 21 under Peptide 2 in particular). Also, the `886 patent teaches a 26 amino acid fragment comprises 23 amino acid from amino acids 35-58 of human CD9 (i.e., aa 36-58) (see patented SEQ ID NO: 7 in particular). Finally, the `886 patent teaches a polypeptide fragment comprises 29 amino acids of 164-192 of human CD9, wherein said polypeptide comprises claimed SEQ ID NO: 3, PKKDV (see patented SEQ ID NO: 6 and col., 21, under peptide 3 in particular).

The reference teachings anticipate the claimed invention.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over US. Pat. No. 5,439,886 in view of U.S. Patent No. 6,472,520.

The teachings of the `886 patent have been discussed, supra. The `886 patent further peptides 2 and 3 showed an inhibitory activity in a concentration-dependent manner (see example 4 and Fig. 8 in particular).

The claimed invention differs for the `886 patent teachings only the recitation of a chimeric protein in claim 75.

The `520 patent teaches a polypeptide can comprise a linker or other sequence for ease of synthesis, purification or identification of the polypeptide (e.g., poly-His or hemagglutinin), or to enhance binding of the polypeptide to a solid support. Fusion proteins capped with such peptides may also be resistant to intracellular degradation in E. coli. Protein fusions, for example, polypeptides conjugated to an immunoglobulin Fc region or a leucine zipper domain (Column 45, lines 43-55 in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fuse the peptides taught by the `886 patent with a peptide linker, an Fc or a leucine zipper domain as taught by the `520 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because such fusion polypeptide are use for ease of synthesis, purification or identification of the polypeptide, or to enhance binding of the polypeptide to a solid support as taught by the `520 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

16. Claim 73 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 6, 2006

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PATENT EXAMINER